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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,869	07/23/2003	Nicholas Lawrence Abbott	032026-0736	8011
<div>23524 7590 12/12/2007</div> <div>FOLEY & LARDNER LLP 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497</div>				
			EXAMINER	
			LUNDGREN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1639	
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			12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,869	ABBOTT ET AL.	
	Examiner	Art Unit	
	Jeff Lundgren	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/1/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-10 and 14-23 are pending in the instant application, and are the subject of the Office Action below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and all dependent claims, are indefinite for reciting the phrases “biochemical blocking compound” and “biochemical blocking layer” because one of ordinary skill in the art could not reasonably determine the metes and bounds of these limitations. The phrases are neither art-specific nor defined in the specification; the phrases are generic and do not allow one to distinguish between compositions that are “biochemical” and serve the purpose of “blocking.” Furthermore, it is not clear if the compound/layer is of biochemical origin, or if the compound/layer blocks molecules of biochemical origin.

Claim 1, and all dependent claims, are indefinite for reciting the term “biochemical” because one of ordinary skill in the art could not reasonably determine the metes and bounds of this limitation. The term “biochemical” while being an art-accepted term, has a range of meanings, none of which clearly define a class of chemicals having a common core, structure or genus. The specification also does not define this term, and only lists a limited number of examples (see paragraph 0063). For example, one of ordinary skill in the art could reasonably argue that a synthetic oligopeptides of 20 amino acids having a man-made sequence is a biochemical because it comprises amino acids residues bound via peptide bonds, while another person of ordinary skill in the art could just as reasonably argue that it is not a biochemical

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because it has no biological origin. Molecules such as CO₂, steroids, and phospholipids, also may or may not be considered biochemicals.

Claim Rejections - 35 USC § 102 – Necessitated by Amendment

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-9 and 14-23, are rejected under 35 U.S.C. § 102(e) as being anticipated by Abbott *et al.*, U.S. Patent No. 6,284,197 B1, issued on September 4, 2001. This rejection is presented in modified form due to Applicants amendments to the claims.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. § 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR § 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR § 1.131.

In their reply, Applicant alleges that the invention as claimed in amended claim 1 is not the same as the device disclosed in Abbott because of the particularly claimed surface. For example, Applicants amendment introduces a specific group of chemical substituents that are selected for the blocking layer, including polymers such as poly(ethylene oxide).

This argument has been considered, but is not found persuasive.

As in claim 1, Abbott does teach the polymer poly(ethylene oxide), although Abbott recites its synonym “poly(ethylene glycol)” (Abbott, col. 17, line 62 through col. 18, line 3).

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Applicant further alleges that Abbott does not anticipate the claimed invention because Abbott is not directed to a device having "a surface of the biochemical blocking layer" that is a "rubbed surface." Applicant suggests that Abbott only teaches rubbing the surface of the substrate.

Applicant's arguments have been considered, but are not persuasive.

Applicant is incorrect in the above assertions for at least two reasons. First, Applicants claims:

"...wherein *a surface of the biochemical blocking layer is a rubbed surface* that possesses features that drive a uniform alignment of liquid crystals when the liquid crystals contact the rubbed surface,"

Claim 1, lines 11-13 (emphasis added). This claim limitation therefore encompasses a biochemical layer positioned on a pre-rubbed surface. For example, see claim 3 wherein such is claimed. If Applicants wishes to claim what is suggested, Applicants may wish to use language similar to "wherein the biochemical compound has been rubbed."

Second, Abbott does teach surfaces having biochemical blocking compounds that have been rubbed:

"Control of the anchoring of mesogens has been largely based on the use of organic surfaces prepared by *coating surface-active molecules or polymer films on inorganic* (e.g., silicon oxide) substrates *followed by surface treatments such as rubbing*. Other systems which have been found useful include surfaces prepared through the reactions of organosilanes with various substrates. See, for example, Yang et al., In, MICROCHEMISTRY: SPECTROSCOPY AND CHEMISTRY IN SMALL DOMAINS; Masuhara et al., Eds.; North-Holland, Amsterdam, 1994; p.441."

Abbott, col. 18, lines 33-42 (emphasis added).

Regarding Applicant's arguments directed to inherency, such arguments are inapposite because Abbott clearly teaches the claimed invention with the explicit recitation of the words in the claims.

Amended claim 1 is directed towards a rubbed substrate structure for use in a liquid crystal assay device, comprising:

(a) a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and

(b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer,

wherein the biochemical blocking layer comprises biochemicals, wherein the biochemical blocking compound is selected from the group consisting of a protein, a zwitterionic polymer, an adsorbed lipid layer, a sugar, a cross-linked lipid, a polyethyleneoxide, a polyoxazoline, and a hydrogel,

wherein a surface of the biochemical blocking layer is a rubbed surface that possesses features that drive a uniform alignment of liquid crystals when the liquid crystals contact the rubbed surface,

wherein the biochemical blocking layer resists non-specific adsorption of non- target species, and

further wherein the biomolecule recognition agent comprises a recognition site capable of selectively recognizing a target species.

Abbott discloses a device and methods for detecting analytes (see e.g. Abstract; col. 1, lines 22-27; col. 5, lines 13-59; col. 6, lines 54-65; col. 13, lines 4-31; col. 14, lines 6-32). In general, the device is multilayered and comprises one or more substrates, an organic layer, a recognition moiety, and a mesogenic layer (see col. 5, lines 13-59; col. 13, lines 4-31; col. 14, lines 6-32). The substrate includes materials such as glass or organic polymers (see col. 6, lines 54-65; col. 14, line 45 thru col. 15, line 10; col. 15, line 59 thru col. 16, line 14; and Fig. 2).

The surface of the substrate disclosed by Abbott is patterned with features such as grooves and ridges with emphasis on the texture:

“The nature of the surface of the substrate has a profound effect on the anchoring of the mesogenic layer which is associated with the surface. The surface can be engineered by the use of mechanical and/or chemical techniques. The surface of each of the above enumerated substrates can be substantially smooth. Alternatively, the surface can be roughened or patterned by *rubbing*, etching, grooving, stretching, oblique deposition *or other similar techniques known to those of skill in the art. Of particular relevance is the texture of the surface which is in contact with the mesogenic compounds.*”

Abbott, col. 16, lines 47-57 (emphasis added).

Abbott generally identifies certain techniques for creating these features:

“The *size and complexity of the pattern on the substrate is limited only* by the resolution of the technique utilized and *the purpose for which the pattern is intended*. For example, using microcontact printing, features as small as 200 nm have been layered onto a substrate. See, Xia, Y.; Whitesides, G., *J. Am. Chem. Soc.* 117:3274-75 (1995). Similarly, using photolithography, patterns with features as small as 1 μm have been produced. See, Hickman et al., *J. Vac. Sci. Technol.* 12:607-16(1994). Patterns which are useful in the present invention include those which comprise features such as wells, enclosures, partitions, recesses, inlets, outlets, *channels, troughs, diffraction gratings and the like.*”

Abbott, col. 17, lines 7-18 (emphasis added).

Regarding the blocking layer, Abbott discloses the use of a mixed SAM wherein certain SAM components have blocking groups, such as CF_3 that blocks nonspecific binding (see Example 6; see also Figs. 23 and 24, and description thereof). The organic layer (refers to instant claimed blocking layer) comprises monolayers, bilayers, and multilayers such as self-assembled monolayers (see e.g. col. 17, line 62 thru col. 18, line 4; col. 19, line 19 thru col. 20, line 3), and the organic layer surface activity, *i.e.*, binding characteristics, is altered by attaching a monovalent moiety (refers to the functional limitation of the blocking layer, *i.e.*, block nonspecific adsorption of pathogens to the surface)(see e.g. col. 25, lines 41-56). More specifically, Abbott teaches:

“Thus, in one preferred embodiment, the substrate is glass or an organic polymer and *the surface has been prepared by rubbing. Rubbing can be accomplished using virtually any material including tissues, paper, brushes, polishing paste, etc. In a preferred embodiment, the rubbing is accomplished by use of a diamond rubbing paste.* In another preferred embodiment, the face of the substrate that contacts the mesogenic compounds is a metal layer that has been obliquely deposited by evaporation. In a further preferred embodiment, the metal layer is a gold layer.”

Abbott, col. 16, line 58-67 (emphasis added); and:

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“In addition to the ability of a substrate to anchor a mesogenic layer, an organic layer attached to the substrate is similarly able to provide such anchoring. A wide range of organic layers can be used in conjunction with the present invention. These include organic layers formed from organothiols, organosilanes, ***amphiphilic molecules, cyclodexins, polyols*** (e.g., ***poly(ethyleneglycol), poly(propyleneglycol)***), fullerenes, and ***biomolecules***. Other useful compounds will be apparent to those of skill in the art.”

Abbott, col. 17, line 62 through col. 18, line 3 (emphasis added).

As in claim 2, Abbott teaches depositing the biomolecule on a rubbed surface (see above). As in claim 3, Abbott teaches rubbing the substrate on the same side. As in claim 4, Abbott teaches a support comprising a biochemical blocking layer that are crosslinked (*i.e.*, the polysilanes forms part of the blocking layer; paragraph bridging cols. 15 and 16). As in claim 5, Abbott teaches numerous crosslinkers, including glutaraldehyde (col. 23, line 15 through col. 24, line 33). As in claims 6 and 7, Abbott teaches the spacer (col. 25, lines 8-56).

As in claim 8 and new claims 21-23, Abbott teaches the use of BSA; as further required by claim 8, Abbott also teaches the attachment of the biorecognition element of certain antibodies (Example 1). As in claim 9, Abbott teaches that the biorecognition element may be used to detect the binding to proteins (col. 13, lines 12-17).

As in claims 14 and 15, Abbott teaches glass and silica (see above; and section titled, *B.3 Functionalized SAMs*). As in claim 16, Abbott teaches a antibody recognition agent (see Figure 3F and description thereof). As in claim 17, Abbott teaches the preferred arrangement (see above). As in claim 18, Abbott teaches 4-cyano-4'-pentylbiphenyl (col. 32, lines 7-10). As in claims 19 and 20, Abbott teaches an optical cell (see Figure 3 and description thereof).

Double Patenting Rejection Maintained

The rejection of claims 1, 8, 9, 11, 12, 16, and 20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8-10, and 14 of copending Application No. 10/934,023, is maintained for the reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed device of has overlapping scope since the device of copending Application No.

10/934,023 the instant application is generic to the device of the presently claimed device of copending Application No. 10/934,023, or in other words, claims 1, 8, 9, 11, 12, 16, and 20 are anticipated by claims 1, 8-10, and 14 of copending Application No. 10/934,023. Specifically, the structural features of both devices are a multilayered support comprising a biochemical blocking layer, a binding agent, and a liquid crystal compound. Thus, the examined claims would have been obvious over the claims of copending Application No. 10/934,023.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 1-10 and 14-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,692,699, in view of Abbott *et al.*, U.S. Patent No. 6,284,197 B1, issued on September 4, 2001.

The scope and content of the instant claims, as well as the teachings in Abbott, are recited in the rejection under 35 USC § 102 above, and are hereby incorporated by reference.

Claim 1 of U.S. Patent No. 6,692,699 recites:

“A rubbed substrate structure for use in a liquid crystal assay device, comprising: (a) a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer, wherein a surface of the biochemical blocking layer is rubbed surface that possesses features that drive a uniform anchoring of liquid crystals Is when the liquid crystals contact the rubbed surface, wherein the biochemical blocking layer resists non-specific adsorption of non-target species, wherein the biomolecule recognition agent is immobilized on the support by being bonded to the biochemical blocking compound, and further wherein the biomolecule recognition agent comprises a recognition site capable of selectively recognizing a target species.”

Claim 9 recites:

“The rubbed substrate structure for use in a liquid crystal assay device according to claim 1, wherein at least two regions of the rubbed surface are rubbed under different pressures, speeds, or for different lengths whereby the at least two regions of the rubbed surface have different sensitivities towards the target species.”

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because each of the claims in the '699 patent, and the teachings in Abbott are directed to the formation of a liquid-crystal based biosensor. One of ordinary skill in the art would have recognized the advantages of using the specific blocking layers of Abbott in view of the invention as claimed in the '699 patent claims for the purposes of reducing adsorption artifacts into the sensing scheme. Accordingly, the invention as claimed in *prima facie* obvious.

Conclusions

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported *in ipsius verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

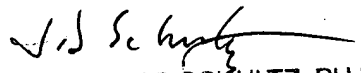
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JSL/


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SUPERVISORY PATENT EXAMINER